PUBLIC VERSION

IN THE UNITED STATES DISTRICT
COURT FOR THE EASTERN DISTRICT
OF TEXAS MARSHALL DIVISION

ALLERGAN, INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC., ET AL.,

Defendants.

Civil Action No. 2:15-cv-1455-WCB

LEAD CASE

FILED UNDER SEAL

DEFENDANTS' MOTION TO DISMISS FOR LACK OF STANDING OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT OF INVALIDITY UNDER 35 U.S.C. § 102(f)

CONFIDENTIAL UNDER PROTECTIVE ORDER

PUBLIC VERSION

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Undisputed facts show that, more than seven years before the patents-in-suit were filed, Dr. Shulin Ding invented the Restasis formulation recited in every claim in the patents-in-suit. Yet, despite her fundamental role in conceiving the claimed subject matter, Dr. Ding was not named as an inventor on any of the patents-in-suit and did not assign—or promise to assign—her rights in the patents-in-suit to Allergan. As a consequence, Allergan lacked standing to sue and lacks standing to maintain this suit because it did not have *any* ownership interest in any of the patents-in-suit when it filed its complaint. Defendants[1] therefore move to dismiss.

Alternatively, Defendants move for summary judgment of invalidity of each of the patents-in-suit under 35 U.S.C. § 102(f) for failing to properly name the inventive entity.

STATEMENT OF UNDISPUTED FACTS

At issue in this case are proposed generic versions of Allergan's topical cyclosporin ophthalmic emulsion sold under the brand name Restasis. Amended Complaint ¶ 4. Restasis contains cyclosporin at a concentration of 0.05% emulsified in a 1.25% castor oil vehicle. *Id.* and Ex. 1, 3.2.P.3.2 Batch Formula. Since approval of the Restasis NDA, Allergan has listed eight patents in the Orange Book and declared that the claims of each of those patents cover Restasis. First, Allergan Orange Book listed (i) a method of treatment patent invented by Dr. Kaswan that issued in 1989 and expired in August of 2009, and (ii) a formulation patent invented by Dr. Ding that issued in 1995 and expired in May of 2014. Ex. 2, U.S. Patent No. 4,839,342 and Ex. 3, U.S. Patent No. 5,474,979; Ex. 4, Ding Dep. Ex. 4 at 3. Allergan subsequently listed the six patents-in-suit[2], which also claim methods of treatment and formulations. Allergan accuses the

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[1] Moving Defendants include Teva Pharmaceuticals USA, Inc.; Innopharma, Inc.; Famy Care, Ltd.; Akorn, Inc.; Mylan Pharmaceuticals; and Mylan, Inc.

[2] The current patents-in-suit are U.S. Patent Nos. 8,629,111 ("the '111 patent," Ex. 5); 8,633,162 ("the '162 patent," Ex. 6); 8,642,556 ("the '556 patent," Ex. 7); 8,648,048 ("the '048 patent," Ex. 8);

Defendants of infringing those patents in the present suit. Complaint ¶ 1. Each claim of the patents-in-suit recites a composition or method of using a composition containing 0.05% cyclosporin and 1.25% castor oil. *See* Exs. 5-10.

I. DR. DING CONCEIVED THE EMULSION FORMULATIONS USED IN ALLERGAN'S CLINICAL TRIALS AND MARKETED AS RESTASIS

Dr. Ding worked at Allergan from 1987 to 1998. Ex. 11, Ding Dep. Tr. at 9:2-5. While there, she worked as a formulator and, in this capacity, her responsibilities were "to formulate, develop, develop formulations and early analytical method [*sic*] to support R&D activity." *Id*. at 11:6-8. Dr. Ding also confirmed that starting in "'93 or '94" she began work on "the development of Restasis," and brought "formulation expertise" to the project. *Id*. at 14:5-11 and 16:19-21. Dr. Ding was the "Pharmaceutical Sciences Point Person" for Allergan's Restasis project which was "meant to develop something to treat dry eye." Ex. 12, Allergan Regulatory Affairs Memorandum at AGN_RES0770592; Ex. 13, Chang Dep. Tr. at 83:2-17; Ex. 11 at 22:4-22.

Allergan filed the application that became the '979 patent, based on Dr. Ding's work correctly named Dr. Ding as an inventor. Ex. 11 at 53:16-54:19. Dr. Ding's '979 patent claims ophthalmic formulations containing a range of cyclosporin from "about 0.05% to and [*sic*] about 0.40%" and castor oil from "about 0.625% by weight, and about 5% by weight." Ex. 3 at claims 7 and 8. The claimed formulation of the patents-in-suit falls within the scope of the claims of Dr. Ding's '979 patent as follows:

8,685,930 ("the '930 patent," Ex. 9); and 9,248,191 ("the '191 patent," Ex. 10). Each of the patents-in-suit claims priority to September 15, 2003.

Restasis® Formulation	**Asserted Patent Formulation Limitations**	**Claim 7 of the '979 Patent**	**Claim 8 of the '979 Patent**
Restasis® (cyclosporine ophthalmic emulsion)	A topical ophthalmic emulsion comprising	A pharmaceutical emulsion suitable for topical application to the ocular tissue comprising of	A pharmaceutical emulsion suitable for topical application to ocular tissue consisting of
Cyclosporine, USP, 0.05% w/w	cyclosporine A in an amount of about 0.05% by weight	cyclosporin A in an amount of between about 0.05 to about 0.40%, by weight	cyclosporin A in an amount of between about 0.05 to about 0.40%, by weight
Castor Oil, USP, 1.25% w/w	castor oil in an amount of about 1.25% by weight	castor oil in an amount of between about 0.625% and about 5.0%, by weight	castor oil in an amount of between about 0.625% and about 5.0%, by weight
Polysorbate 80, NF, 1.0% w/w	polysorbate 80 in an amount of about 1.0% by weight	polysorbate 80 in an amount of about 1.0% by weight	polysorbate 80 in an amount of about 1.0% by weight
Carbomer Copolymer Type A, NF, 0.05% w/w	acrylate/C10-30 alkyl acrylate cross-polymer in an amount of about 0.05% by weight	Pemulen in an amount of about 0.05% by weight	Pemulen in an amount of about 0.05% by weight
Castor Oil, USP, 1.25% w/w	glycerine in an amount of about 2.2% by weight	glycerine in an amount of about 2.2% by weight	glycerine in an amount of about 2.2% by weight
1 N Sodium Hydroxide, USP	sodium hydroxide	--	--
Purified Water, USP	water	Water	water
pH 7.2-7.6	pH in the range of about 7.2 to about 7.6	--	pH of between 7.2-7.6

Compare *Id*. to Ex. 1, 3.2.P.3.2 Batch Formula and *e.g.*, the '111 patent, claims (Ex. 5). Indisputably, the Restasis formulation falls within the scope of the '979 patent's claims. Ex. 14, Maness Dep. Tr. at 174:5-176:14. Allergan listed the '979 patent in the FDA Orange Book as covering Restasis and thereby enjoyed the statutory benefits of so doing. Ex. 4 at 3.

As of 1994, Dr. Ding and her '979-patent co-inventors had solved several problems related to ophthalmic emulsions of cyclosporin, including eye irritation, oil residue, vision

blurring, and low bioavailability. Ex. 3, 2:5-57. Dr. Ding reported that such emulsions have a "high comfort level and low irritation potential." Ex. 3, 2:65-3:3.

II. DR. DING CONCEIVED OF THE EMULSION FORMULATIONS USED IN ALLERGAN'S CYCLOSPORIN PHASE III CLINICAL TRIALS, INCLUDING THE FORMULATION CLAIMED IN THE PATENTS-IN-SUIT

Less than a year after the '979 patent issued, Dr. Ding both conceived of, and actually reduced to practice, the precise formulation that became Restasis. Dr. Ding testified that "as part of the project team for Phase 3 [testing of Restasis, she] came up with formulations for Phase 3." Ex. 11 at 109:7-14. One of the two cyclosporin formulations tested in Phase 3 eventually became Restasis. *See* Ex. 15, *Ophthalmic Cyclosporine (Restasis) for Dry Eye Disease*, The Medical Letter on Drugs and Therapeutics, Vol. 45, May 26, 2003.[3]

A. The Ton-Ha laboratory notebook entries corroborate Ding's inventorship

During her deposition, Dr. Ding confirmed that, while at Allergan, she conducted experiments using varying amounts of cyclosporin—including 0.05% —with a constant emulsion vehicle containing 1.25% castor oil. Ex. 11 at 99:9-100:4, 101:15-22.

Also at her deposition, Dr. Ding discussed the laboratory notebook of Ton-Ha who, Dr. Ding testified, was "one of the staff supporting [Dr. Ding's] work" and working "under [Dr. Ding's] guidance." Ex. 11 at 93:3-8, 94:3-10, discussing Ton-Ha's laboratory notebook.

Dr. Ding stated that she arrived at the "Xnumber: 9054" formulation in August of 1996. Ex. 11 at 96:25-97:11; 99:9-21 (discussing Ex. 16, a portion of Ton-Ha's laboratory notebook). The formulation for "Xnumber:9054" as it appears in Ton-Ha's laboratory notebook and confirmed by Dr. Ding is reproduced below:

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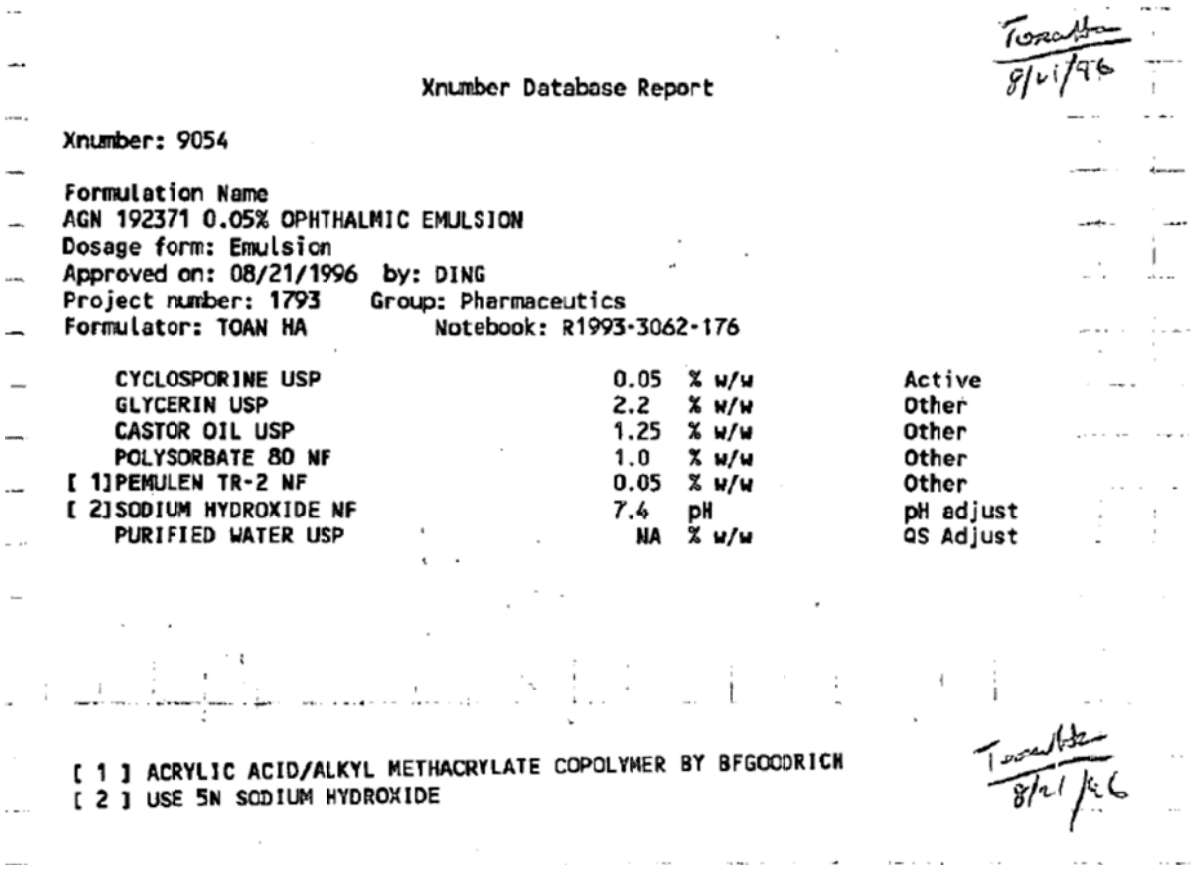
[3] Notably, the amounts of CsA and castor oil contained Restasis formulation, as well as their ratio to each other, fall squarely within the "more prefer[ed]" range recited in Dr. Ding's '979 Patent. Ex. 3, 3:17-20.



Xnumber Database Report

Xnumber: 9054

Formulation Name
AGN 192371 0.05% OPHTHALMIC EMULSION
Dosage form: Emulsion
Approved on: 08/21/1996 by: DING
Project number: 1793 Group: Pharmaceutics
Formulator: TOAN HA Notebook: R1993-3062-176

CYCLOSPORINE USP	0.05	% w/w	Active
GLYCERIN USP	2.2	% w/w	Other
CASTOR OIL USP	1.25	% w/w	Other
POLYSORBATE 80 NF	1.0	% w/w	Other
[1]PEMULEN TR-2 NF	0.05	% w/w	Other
[2]SODIUM HYDROXIDE NF	7.4	pH	pH adjust
PURIFIED WATER USP	NA	% w/w	QS Adjust

[1] ACRYLIC ACID/ALKYL METHACRYLATE COPOLYMER BY BFGOODRICH
[2] USE 5N SODIUM HYDROXIDE

Ex. 16, Ton-Ha Laboratory Notebook at AGN_RES0781930.

Formulation "Xnumber: 9054" is *identical* to "Composition II" disclosed and claimed in each of the patents-in-suit. "Compare Xnumber: 9054" to *e.g.* Ex. 5, "Composition II" at 14:20-30. Composition II, which appears in the specification of all of the patents-in-suit, is reproduced below:

	Composition I wt %	Composition II wt %
Cyclosporin	0.1	0.05
Castor Oil	1.25	1.25
Polysorbate 80	1.00	1.00
Premulen ®	0.05	0.05
Glycerine	2.20	2.20
Sodium hydroxide	qs	qs
Purified Water	qs	qs
pH	7.2-7.6	7.2-7.6
Weight Ratio of Cyclosporin A to Castor Oil	0.08	0.04

Representative claim 1 of the '111 patent claims Composition II:

> 1. A topical ophthalmic emulsion for treating an eye of a human comprising cyclosporin A in an amount of about 0.05% by weight, polysorbate 80, acrylate/C10-30 alkyl acrylate cross-polymer, water, and castor oil in an amount of about 1.25% by weight; wherein cyclosporin A is the only peptide present in the topical ophthalmic emulsion.

Ex. 5 at 15:14-20.

Most notably, the formulation of "Xnumber:9054" contains 0.05% cyclosporin and 1.25% castor oil. Ex. 16. Indeed, "Xnumber:9054" has *all of the exact same ingredients*, in the *same amounts*, with the *same pH* range and was formulated to achieve the *same goal* as the Restasis formulation recited in each claim of the patents-in-suit. *Id.*; Ex. 11 at 22:4-22. Dr. Ding conceived of this in August 1996, more than seven years before the earliest priority date of the patents-in-suit. Ex. 16 and Ex. 11 at 99:9-21.

B. Dr. Ding's Technical Report dated January 14, 1997, corroborates Ding's inventorship

At her deposition, Dr. Ding also testified about a "Technical Report" she authored, which is date-stamped January 14, 1997. Ex. 17, Technical Report No. PD-1996-017. After confirming that she authored the Technical Report, Dr. Ding acknowledged the report referred to two

different concentrations of cyclosporin "that had been tested, yes, in Phase 2. [And were] moving toward Phase 3 now." Ex. 11 at 143:10-19. Dr. Ding also confirmed during deposition that formulation "Xnumber: 9054" from Ton-Ha's laboratory notebook (discussed above) is the same as formulation "9054X" referred to in Dr. Ding's Technical Report, excerpted below:

PD-1996-017
S. Ding
Page 3 of 20

I. SUMMARY

A sterile cyclosporine emulsion eye drop is being developed by Allergan Pharmaceutical R&D for the treatment of keratoconjunctivitis sicca. The product has been tested in a Phase II clinical study and is moving into Phase III development. The concentrations selected for the Phase III pivotal studies are 0.05% (9054X) and 0.1% (8735X).

Ex. 17. at 3; Ex. 11 at 143:1-144:19.

Q: So, this 9054 number that you see, the X number?

Dr. Ding: Uh-huh.

Q: Is that, .05 percent, is that referring to, that number in your report the same number?

Dr. Ding: Yes.

Q: So, does that mean that this stuff that is found in the [Ton-Ha] notebook is the thing that is, that had been tested in phase 2 clinical studies and they were selected for the phase 3 studies?

Dr. Ding: Yes.

Ex. 11 at 144:7-19.

Dr. Ding's testimony confirms that the "Xnumber:9054" formulation she had created in August of 1996 was the exact same formulation referred to as "9054X" and carried through to Phase 3 trials after January 1997. There is no dispute that this formulation ultimately became Restasis. Ex. 1, 3.2.P.3.2 Batch Formula.

C. Dr. Ding's handwritten notes on Allergan's draft technical report further corroborate Ding's inventorship

In response to Defendants' subpoena, Dr. Ding produced, *inter alia*, a draft technical report containing handwritten notes and edits. *See* Ex. 18, Technical Report No. PA-1998-033. At her deposition, Dr. Ding confirmed that the handwriting was her own and the document was her own. Ex. 11 at 172:9-17. In her handwritten edits of the draft technical report, Dr. Ding struck through a sentence in a paragraph referring to "cyclosporine ophthalmic emulsion 0.1% (8735X)" and "cyclosporine ophthalmic emulsion 0.05% (9054X)." As she confirmed at her deposition, Dr. Ding wrote by hand, "[t]he two formulations are similar in every regard with [the] exception of cyclosporine concentration." Ex. 11 at 173:25-174:5 and Ex. 18 at DING_0005. The draft report was signed by Dr. Ding and two other Allergan employees on September 17, 1998. Ex. 18 at DING_0001.

Dr. Ding's handwritten notes confirm that the formulation of 9054X is identical to the formulation of "Xnumber: 9054" conceived by Dr. Ding during or before August 1996. And as discussed above, this very same formulation was the subject of the patent applications that led to the each claim of the patents-in-suit. See § II.A.

D. Other Allergan witnesses corroborate Dr. Ding's inventorship of the Restasis formulation

Other Allergan witnesses also corroborate Dr. Ding's role in the invention of Restasis, *including the named inventors* on the patents-in-suit. For example, Dr. James Chang, a former Allergan employee and a named inventor on the patents-in-suit testified:

> **Q.** You were not involved in selecting the components for Restasis or the amounts of those components?
>
> **A.** To the best of my recollection, the whole development was done in around mid-1990s. At the time it was the scientist in the department by the name of Shulin Ding who was the formulator, and I was not even in that department from early '94 to the end of 1997.

Ex. 13 at 10:17-10:25.

Q. Did Shulin Ding come up [with the 0.05% and 0.1% CsA] formulations?

A. Yes, based on my understanding.

Ex. 13 at 99:13-99:17.

Similarly, David Power, another former Allergan employee and named inventor on the patents-in-suit testified that "[t]here was a team member named Shulin Ding at the time that was working on formulations, so I would assume it was Shulin that came up with the [0.05 CsA/1.25% castor oil] original formulations." Ex. 19, Power Dep. Tr. at 54:2-54:5.

And Diane Tang-Liu, a third named inventor on the patents-in-suit testified:

Q. Is it fair to say that Shulin Ding is the lead individual in your understanding who is responsible for the development of the Restasis formulation?

A. She was the key, if not one of the key contributors.

Ex. 20, Tang-Liu Dep. Tr. at 274:20-275:2.

ARGUMENT

I. DR. DING INVENTED THE FORMULATION RECITED IN EVERY CLAIM OF THE PATENTS-IN-SUIT

Dr. Ding conceived of the claimed formulations more than seven years before the earliest priority date of the patents-in-suit. *See* Undisputed Facts, §II, above. "Conception is the touchstone of inventorship, the completion of the mental part of invention." *Burroughs Wellcome Co. v. Barr Labs*., Inc., 40 F.3d 1223, 1227 (Fed. Cir. 1994). "Conception is the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1460 (Fed. Cir. 1998) (citation and internal quotation marks omitted). Dr. Ding's sworn testimony together with the corroborating documents and testimony of others establish that Dr.

Ding conceived of Composition II of the patents-in-suit. And each claim of the patents-in-suit recites Composition II. Accordingly, Dr. Ding should have been named as an inventor on each of the patents-in-suit, as detailed below.

A. Dr. Ding invented the 9054X formulation which is the same as Composition II claimed in the patents-in-suit, which is the same as Restasis

There is no dispute that Dr. Ding is a properly named inventor on the Ding '979 patent. The '979 patent covers various formulations that Allergan tested in its Phase II dose-ranging clinical trials[4]. Ex. 11 at 108:12-18; Ex. 3. And as the lead formulator on the team, Dr. Ding carried her research forward and also developed the formulations Allergan tested in its Phase III trials, including Composition II from the patents-in-suit. Dr. Ding testified:

> **Q.** And as part of the project team for Phase 3 you came up with the formulations for Phase 3, right?
>
> **A**. Yes.

Ex. 11 at 109:11-14.

> Q. You were the one that figured out what different amounts of cyclosporin and castor oil and Polysorbate 80 and Pemulen should go in based upon formulation, right?
>
> A. Yes.

Id. at 148:1-6.

As noted above, the 9054X formulation and Composition II from the patents-in-suit are identical. *See* Undisputed Facts, § II above. Therefore, Dr. Ding conceived of the Composition II formulation by August 1996 because her assistant, working "under [Dr. Ding's] guidance," *actually made* the formulation by then. *Id*; Ex. 11 at 93:3-8, 94:3-10. And as noted above, the Composition II formulation is recited in every claim of the patents-in-suit. *See* Undisputed Facts,

[4] As noted above, Restasis also falls within the scope of the '979 patent claims.

§ II, above. Accordingly, Dr. Ding's creation of the 9054X formulation (Composition II of the patents-in-suit) establishes that Dr. Ding conceived the formulation recited in every asserted claim in this litigation.

B. Dr. Ding's inventorship is corroborated by documents and others' testimony

Ample documentary evidence and testimony corroborate Dr. Ding's inventorship of the 9054X formulation for use in treating dry eye. "Documentary or physical evidence that is made contemporaneously with the inventive process provides the most reliable proof that the inventor's testimony has been corroborated." *Sandt Tech., Ltd. v. Resco Metal and Plastics Corp*., 264 F.3d 1344, 1350–51 (Fed. Cir. 2001). First, Ton-Ha's laboratory notebook shows that, Ton-Ha "one of the staff supporting [Dr. Ding's] work" and working "under [her] guidance," actually reduced the 9054X formulation to practice in August 1996. Ex. 11 at 93:3-8, 94:3-10; Ex. 16. Second, Dr. Ding authored a technical report that documents that the 9054X formulation was selected to move forward to Phase 3 clinical trials *before* the patent-in-suit were filed. Ex. 17 at AGN_RES0118795; Ex. 11 at 143:1-144:19. Third, Dr. Ding's editorial notes on an Allegan draft technical report further support Dr. Ding's testimony that she "came up with the formulations for Phase 3." *Id*. at 109:11-14.

Likewise, *the named inventors* on the patents-in-suit attribute the formulation to Dr. Ding. James Chang, David Power, and Diane Tang-Liu each admitted that Dr. Ding was responsible for coming up with the Restasis formulation. *See* Undisputed Facts, § II above. The testimonies of the named inventors of the patents-in-suit, together with the documents discussed above provide corroboration that Dr. Ding invented the formulation recited in the claims-at-issue.

C. Dr. Ding is the only correct inventor of any of the Patents-in-Suit

The mere discovery of obvious properties of, or recognizing effects that naturally flow from administration of, Dr. Ding's formulation cannot allow inventorship to vest with any of the named inventors on the patents-in-suit. "We find it implausible to say that a person who contributed only to the non-novel and/or obvious elements of a claim can be called an inventor." *Levin v. Septodont Inc.*, 34 F. App'x 65, 73 (4th Cir. 2002); *see also Garrett Corp. v. U. S.*, 190 Ct.Cl. 858, 422 F.2d 874 (Ct.Cl.1970)(holding that even though the claim at issue included a specific reference to an alleged contribution of an individual, the person who suggested the idea was not a joint inventor because that idea was "obvious in view of the prior art."); *see also Pannu v. Iolab Corp.*, 155 F.3d 1344, 1351 (Fed. Cir. 1998).

Each of the asserted claims recites an ophthalmic emulsion comprising 0.05% CsA and 1.25% castor oil or methods of its use in treating dry eye and related conditions. As demonstrated above, there is clear and convincing evidence that Dr. Ding conceived of each of these limitations. Aside from the formulation itself, some of the claims within the patents-in-suit recite additional limitations or combinations of limitations (the dosing schedule, efficacy, side effect/adverse event, and comparator limitations)[5]. But each of these additional limitations would

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[5] These additional limitations include:

- twice daily dosing
- when the topical ophthalmic emulsion is administered to the eye of a human, "the blood of the human has substantially no detectable concentration of the [CsA]" (*See e.g.* Ex. 6, Claims 11 and 21);
- the emulsion is "effective/therapeutically effective at treating keratoconjunctivitis sicca" (*See e.g.*, Ex. 9, Claim 1);
- the emulsion is "therapeutically effective in treating dry eye" (*See e.g.*, Ex. 9, Claim 13);
- the emulsion is "effective/therapeutically effective in increasing tear production" (*See e.g.*, Ex. 9, Claim 25);
- the emulsion "is as substantially therapeutically effective/achieves at least as much therapeutic effectiveness as a second emulsion administered to a human in need thereof at a frequency of twice a day, the second emulsion comprising [CsA] in an amount of 0.1% by weight and castor

have been an inherent and otherwise obvious feature of the formulation invented by Dr. Ding, and each was well known in the art, as discussed below. Ex. 14 at 134:19-24; see also Ex. 21, Hanes Expert Report, ¶¶132-448 and Ex. 22, Calman Expert Report, ¶¶212-686.

Indeed, Allergan's expert, Dr. Maness admitted that "the clinical properties of [Restasis] flow from the administration of the formulation to the patients." Ex. 14 at 134:19-24. And Allergan's technical experts offer no rebuttal to the Defendants' experts' testimony that the prior art taught the efficacy and side effect/adverse event limitations. Ex. 23, Perry Expert Report, ¶¶156-201; Ex. 24, Loftsson Expert Report, ¶¶72-125.

Even the named inventors of the patents-in-suit admit they had no inventive role in the development of Restasis. For example, regarding the invention of Restasis, James Chang stated "No, I don't have any part in that invention." Ex. 13 at 9:23-10:16. Similarly, regarding his role in the invention, David Power testified, "my input and my part of that was requiring that it be in a liquid form of suitable viscosity, pH and stability." Ex. 19 at 40:19-40:23. But specifying that the ophthalmic emulsion be a liquid with suitable viscosity, pH, and stability certainly does not rise to the level of inventorship because such characteristics would have been obvious in view of

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oil in an amount of 1.25% by weight" (*See e.g.*, Ex. 6, Claim 13);

- the "emulsion breaks down more quickly in the eye of a human, once administered to the eye of the human, thereby reducing vision distortion in the eye of the human as compared to a second topical ophthalmic emulsion that contains only about 50% as much castor oil" (*See e.g.*, Ex. 6, Claim 15);
- the "emulsion is effective in enhancing/restoring lacrimal gland tearing" (*See e.g.*, Ex. 10, Claim 16);
- the "method demonstrates a reduction in adverse events in the human, compared to administration of a second topical ophthalmic emulsion to a human eye on need thereof at a frequency of twice a day, the second topical ophthalmic emulsion comprising [CsA] in an amount of about 0.1% by weight and castor oil in an amount of about 1.25% by weight" (*See e.g.*, Ex. 10, Claim 21);
- "the adverse events are selected from the group consisting of visual distortion and eye irritation" (*See e.g.*, Ex. 10, Claim 23).
- the emulsion is "administer[ed] …at a frequency of twice a day" (*See e.g.*, Ex. 10, Claims 1, 13, 17, and 21)

the art. *Levin.* 34 F. App'x at 73. A joint inventor must "do more than merely explain to the real inventors well-known concepts and/or the current state of the art." *Pannu,* 155 F.3d at 1351. "One who merely suggests an idea of a result to be accomplished, rather than means of accomplishing it, is not a joint inventor." *Garrett Corp. v. U. S.*, 422 F.2d 874 (Ct. Cl. 1970*). See also Amax Fly Ash Corp. v. U.S.*, 514 F.2d 1041, 1047 (Ct. Cl. 1975) (stating that the conception required for inventorship "must be more than the realization of a desirable result, and more than a mere hope or expectation" (internal citations omitted). Accordingly, Dr. Ding is the only person who should be named as an inventor on the patents-in-suit. In the alternative, should the Court disagree that Dr. Ding is the sole inventor of the patents-in-suit, at the very least she should have been named as a joint inventor for the reasons articulated in Undisputed Facts § II, above.

II. ALLERGAN LACKS STANDING TO MAINTAIN THIS LAWSUIT

A. Allergan Does Not Have Article III Standing To Sue For Infringement Because It Lacks Any Ownership Interest in the Patents-In-Suit

A federal court may exercise jurisdiction over a case only if the plaintiff can demonstrate that it had Article III standing "on the date it file[d] suit." *Abraxis Bioscience, Inc. v. Navinta LLC*, 625 F.3d 1359, 1363-64 (Fed. Cir. 2010); *see also Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) (holding that "[t]he party invoking federal jurisdiction bears the burden of establishing the[] elements" of standing); *Sicom Sys., Ltd. v. Agilent Techs., Inc.*, 427 F.3d 971, 976 (Fed. Cir. 2005) (same); *Script Sec. Sols., LLC v. Amazon.com, Inc.*, No. 2:15-CV-1030-WCB, 2016 WL 6433776, at *2 (E.D. Tex. Oct. 31, 2016) (Bryson, J.) (noting that, when a defendant raises a factual challenge to jurisdiction, "[t]he party asserting federal jurisdiction must establish standing under the preponderance of the evidence standard"). "[I]n a patent infringement action, 'the plaintiff must demonstrate that it held enforceable title to the patent at

the inception of the lawsuit' to assert standing." *Abraxis*, 625 F.3d at 1364 (quoting *Paradise Creations, Inc. v. UV Sales, Inc.*, 315 F.3d 1304, 1309-10 (Fed. Cir. 2003)). If the plaintiff lacked Article III standing at the outset of the case, the lawsuit must be dismissed for lack of subject-matter jurisdiction; "the jurisdictional defect cannot be cured after the inception of the lawsuit." *Id.* (citation and internal quotation mark omitted); *accord Schreiber Foods, Inc. v. Beatrice Cheese, Inc.*, 402 F.3d 1198, 1203 (Fed. Cir. 2005).

Allergan lacked any ownership interest in the patents-in-suit when it filed suit, and has produced no evidence of such an ownership interest today. As explained above, *see supra* Undisputed Facts, § II, the evidence shows that Dr. Ding is the *sole inventor* of the patents-in-suit. And because "[o]wnership springs from invention," Dr. Ding is presumptively the *sole owner* of those patents as well. *Teets v. Chromalloy Gas Turbine Corp.*, 83 F.3d 403, 407 (Fed. Cir. 1996). Allergan has presented no evidence tending to overcome that presumption.

Specifically, Defendants issued discovery requests to Allergan for, among other things, any documents evidencing an assignment of rights in the patents-in-suit from Dr. Ding to Allergan, including any employment agreements between Dr. Ding and Allergan that might have contained such an assignment (or even an agreement to effect such an assignment). Allergan failed to produce any such documents—a tacit admission that none exist. And since all assignments of rights to patents must be in writing, *see* 35 U.S.C. § 261, Allergan's failure to produce an executed written assignment or other contract precludes it from arguing that Dr. Ding previously assigned to Allergan (or agreed to assign to Allergan) any rights in the patents-in-suit. *See, e.g., Enzo APA & Son, Inc. v. Geapag A.G.*, 134 F.3d 1090, 1093 (Fed. Cir. 1998); *see also Criminal Activity Surveillance, LLC v. ADT Sec. Servs., Inc.*, No. 6:11-CV-494, 2013 WL 11336853, at *2 (E.D. Tex. Mar. 20, 2013) ("[A] generic contract template is insufficient to

show CAS had rights in the '690 Patent when the action was filed—an actual writing is required.").

Because Dr. Ding is the sole owner of the patents-in-suit, *only Dr. Ding* had standing to assert infringement of those patents; Allergan did not, and does not. *See Abraxis*, 625 F.3d at 1364. Allergan's complaint must therefore be dismissed for lack of subject-matter jurisdiction. *See id.* at 1367; *Criminal Activity*, 2013 WL 11336853, at *2.[6]

B. Even if Dr. Ding Were Only a Joint Inventor of the Patents-In-Suit, Allergan Would Lack Standing to Sue Because Ding Has Not Been Joined as a Plaintiff

In addition to demonstrating Article III standing, a plaintiff alleging patent infringement must show that it "possessed standing as defined by § 281 of the Patent Act" at the time the suit was filed. *Alps S., LLC v. Ohio Willow Wood Co.*, 787 F.3d 1379, 1382 (Fed. Cir. 2015). And it is a "settled principle" of patent standing law that "[a]n action for infringement must join as plaintiffs all co-owners." *Ethicon*, 135 F.3d at 1467-68; *accord Gellman v. Telular Corp.*, 449 F. App'x 941, 942 (Fed. Cir. 2011). "Absent the voluntary joinder of all co-owners of a patent, a co-owner acting alone will lack standing." *Israel Bio-Eng'g Project v. Amgen, Inc.*, 475 F.3d 1256, 1264-65 (Fed. Cir. 2007); *accord Speedfit LLC v. Woodway USA, Inc.*, --- F. Supp. 3d ----, 2016 WL 7471307, at *3 (E.D.N.Y. Dec. 28, 2016) ("[T]he Federal Circuit has consistently

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[6] Because standing is analyzed as of the date the plaintiff files suit, a plaintiff without title to a patent may not retroactively cure a standing defect by obtaining a *nunc pro tunc* assignment of patent rights. Accordingly, it is not open to Allergan to attempt to cure its standing problem now by obtaining a retroactive license from Dr. Ding. *See Enzo*, 134 F.3d at 1093-94 ("[P]arties should possess rights before seeking to have them vindicated in court. Allowing a subsequent assignment to automatically cure a standing defect would unjustifiably expand the number of people who are statutorily authorized to sue.") (quoting *Procter & Gamble Co. v. Paragon Trade Brands, Inc.*, 917 F. Supp. 305, 310 (D. Del. 1995)); *accord Abraxis*, 625 F.3d at 1367; *Schreiber Foods*, 402 F.3d at 1203.

required that all co-inventors be joined as plaintiffs at the time that an infringement suit is filed in order for there to be proper standing to proceed with an infringement claim.").

As explained above, *see supra* Undisputed Facts, § II, even if the Court concludes that there are unresolved issues of fact as to whether Dr. Ding is the sole inventor of the patents-in-suit, there can be no real dispute that Dr. Ding is a least a joint inventor—and hence a joint owner—of the patents.[7] *See Ethicon*, 135 F.3d at 1465 ("[I]n the context of joint inventorship, each co-inventor presumptively owns a pro rata undivided interest in the entire patent, no matter what their respective contributions.")(footnote omitted).[8] Accordingly, even if Allergan has a partial ownership interest in the patents by virtue of obtaining assignments from the other inventors of those patents, this lawsuit still must be dismissed for lack of standing because Dr. Ding has not been joined as a plaintiff. *See Gellman*, 449 F. App'x at 944-45 (affirming dismissal of infringement suit for lack of standing because plaintiff was "at best a joint legal owner" of the patent and co-owner was not a party to the suit); *Int'l Nutrition Co. v. Horphag Research Ltd.*, 257 F.3d 1324, 1331 (Fed. Cir. 2001)(affirming dismissal of patent infringement suit because not all co-owners of the patent had joined in the suit); *Ethicon*, 135 F.3d at 1468

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[7] Notably, if Allergan seeks to correct inventorship under 35 U.S.C. § 256 to avoid invalidity under § 102(f), that attempt will effectively constitute an *admission* that Dr. Ding is at least a joint inventor and joint owner of the patents. And even if Allergan is successful in correcting inventorship, that will not remedy the standing defect. *See Bd. of Trustees of Univ. of Illinois v. Micron Tech., Inc.*, No. 2:11-CV-2288-SLD-JEH, 2017 WL 1164483, at *2 (C.D. Ill. Mar. 28, 2017)(noting that a "successful § 256 motion" can "destroy standing" if the newly-named inventor is not a plaintiff in the lawsuit).

[8] As discussed above, Allergan has presented no evidence that would allow it to rebut the presumption that Dr. Ding, as a co-inventor of the patents-in-suit, is also a co-*owner* of the patents.

(same); *Speedfit*, 2016 WL 7471307, at *4 (dismissing infringement suit for lack of standing because co-inventor of patents was not named as a plaintiff).[9]

III. THE PATENTS-IN-SUIT ARE INVALID UNDER 35 U.S.C. § 102(f)

Allergan's failure to name Dr. Ding as an inventor renders each of the patents-in-suit invalid under 35 U.S.C. § 102(f). This subsection "mandates that a patent accurately list the correct inventors of a claimed invention." *Pannu*, 155 F.3d at 1349. "Thus, section 102(f) still makes the naming of the correct inventor or inventors a condition of patentability; failure to name them renders a patent invalid." *Id*. at 1349–50.

Defendants have shown by clear and convincing evidence that by 1996 Dr. Ding had conceived of the formulation recited in every asserted claim. *Supra* Undisputed Facts, § II. Dr. Ding's testimony, multiple corroborating documents, and the testimony of other Allergan witnesses establish that Dr. Ding should have been named as an inventor on each patent-in-suit. But she was not. Accordingly, the patents-in-suit are invalid under 35 U.S.C. § 102(f).

CONCLUSION

For the foregoing reasons, Defendants request that the Court dismiss this lawsuit for lack of standing. In the alternative, Defendants request that the Court find each claim of the patents-in-suit invalid for failing to properly name the inventive entity under 35 U.S.C. § 102(f).

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[9] Defects in patent standing arising from the failure to join co-owners as plaintiffs—like Article III standing defects—cannot be cured through retroactive assignments of patent rights. *See Alps S.*, 787 F.3d at 1385; *Speedfit*, 2016 WL 7471307, at *4; *see also supra note* 5. Thus, Allergan cannot now retroactively cure its lack of standing under the Patent Act by obtaining an assignment of patent rights from Dr. Ding.

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the above and foregoing was served upon all counsel of record via e-mail on May 30, 2017.

/s/ *J.C. Rozendaal*
J.C. Rozendaal

CERTIFICATE OF AUTHORITY TO FILE UNDER SEAL

I certify that, pursuant to Local Rule CV-5(a)(7), the foregoing instrument designated as confidential in accordance with the previously signed Protective Order is authorized by the Court to be filed under seal.

/s/ *J.C. Rozendaal*
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